

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF INDIANA
LAFAYETTE DIVISION

KELLI PAGE,)	CASE NO.: 4:21-cv-00079
)	
Plaintiff,)	
v.)	COMPLAINT FOR DAMAGES
)	AND JURY DEMAND
BOSTON SCIENTIFIC CORPORATION,)	
)	
Defendant.)	

Plaintiff, KELLI PAGE (“Plaintiff”), files this Complaint and for causes of action against Defendant Boston Scientific (the “Defendant”), and alleges as follows:

INTRODUCTION

1. On or about September 19, 2012, at the Franciscan St. Elizabeth Health Hospital in Lafayette, Indiana, Plaintiff KELLI PAGE was surgically implanted with the Boston Scientific Advantage Fit™ pubovaginal mid-urethral sling (the “Advantage Fit” or the “pelvic mesh product”), a pelvic mesh product and medical device designed, manufactured, and marketed by Defendant.

2. Although the Advantage Fit was intended to treat stress urinary incontinence, neither Plaintiff nor her healthcare providers were warned that the Advantage Fit was defective and negligently designed and marketed. As a result of being surgically implanted with Defendant’s unreasonably dangerous defective Advantage Fit pelvic mesh product, Plaintiff has suffered, and continues to suffer, debilitating injuries, as described further herein. In addition and in the alternative, Plaintiff suffered from pre-existing injuries/conditions which were aggravated,

exacerbated, and/or accelerated by implantation of the Advantage Fit device. Plaintiff brings this suit for damages related to those injuries.

JURISDICTION AND VENUE

3. The Court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1332(a) inasmuch as the amount in controversy exceeds \$75,000 and the Plaintiff is a citizen of a different state than the Defendant.

4. Venue in this district for pretrial proceedings in these civil actions is proper under 28 U.S.C. § 1391, inasmuch as a substantial part of the events or omissions giving rise to the claim occurred in this district. Specifically, Plaintiff was implanted with the products at issue in this district at the Franciscan St. Elizabeth Health Hospital in Lafayette, Indiana, and was injured in this district.

5. Defendant is subject to *in personam* jurisdiction in the U.S. District Court for the Northern District of Indiana because Defendant placed defective products in the stream of commerce and all or some of those products were implanted into and caused personal injuries to Plaintiff, an Indiana resident, in the State of Indiana. Each Defendant has sufficient minimum contacts in Indiana or otherwise intentionally avails itself of the Indiana market through, without limitation, its advertisement, promotion, marketing, sales and/or distribution and other business activities, so as to render the exercise of jurisdiction over it by the Indiana courts consistent with traditional notions of fair play and substantial justice.

6. Plaintiff KELLI PAGE is, and was at all times relevant to this suit, a citizen and resident of Lafayette, Indiana.

7. Defendant Boston Scientific Corporation is a Massachusetts corporation with its principal place of business in Massachusetts. At all times material hereto, Boston Scientific was

engaged in the business of developing, manufacturing, licensing, promoting, marketing, distributing, testing, warranting and/or selling in interstate commerce throughout the United States, including Indiana, either directly or indirectly, its medical devices intended to treat stress urinary incontinence and/or pelvic organ prolapse, the Advantage Fit product that was implanted into Plaintiff.

PARTIES

8. Defendant is vicariously liable for the acts and omissions of its employees and/or agents who were at all times relevant hereto acting on behalf of the Defendant and within the scope of their employment or agency with the Defendant.

9. At all times relevant herein, the Defendant was engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, testing, training, marketing, promoting, packaging, labeling, and/or selling such devices, including the Advantage Fit Pelvic Mesh Product. Defendant manufactures, markets, advertises, promotes, and sells products worldwide.

FACTUAL BACKGROUND

The Pelvic Mesh Products

10. At all times relevant herein, Defendant was engaged in the business of developing, designing, licensing, manufacturing, distributing, marketing, packaging, labeling, advertising, delivering, selling and introducing into interstate commerce, including within the United States and within the State of Indiana, either directly or indirectly through third parties or related entities, a line of pelvic mesh products (the “Pelvic Mesh Products”), including the Advantage Fit mesh product, the device implanted into Plaintiff. The Advantage Fit product was designed primarily

for the purpose of treating stress urinary incontinence. All references herein to Pelvic Mesh Products includes the Advantage Fit pelvic mesh product.

11. Stress urinary incontinence (“SUI”) is a type of incontinence characterized by leakage of urine during moments of physical stress, such as coughing, laughing, or sneezing. Although inconvenient, SUI is not life-threatening. At all relevant times, the Advantage Fit was intended to be used, and for Plaintiff was used, to treat stress urinary incontinence.

12. Surgical mesh is a medical device that is generally used to repair weakened or damaged tissue. This is the type of mesh used in Defendant’s Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue in this case. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse (POP) or to support the urethra to treat SUI. Most pelvic mesh products, including the Advantage Fit, are comprised of non-absorbable, synthetic, monofilament polypropylene mesh. Defendant’s Pelvic Mesh Products, including the Advantage Fit pelvic mesh products, were and are specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma, and minimal pain while correcting SUI and POP.

13. Pelvic mesh products used for the surgical management of SUI in women are primarily three different designs: the transobturator sling, the retropubic sling, and the single-incision or “mini sling.” The Advantage Fit sling is a retropubic sling.

14. Prior the implantation of the Advantage Fit pelvic mesh product at issue in this claim, Defendant sought and obtained Food and Drug Administration (“FDA”) approval to market the Advantage Fit under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of medical devices if the device is deemed

substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

15. In 1996, the FDA cleared the first pelvic mesh products for use in the treatment of SUI. These products include products manufactured, marketed, and distributed by Defendant. These products were and are approved by the FDA under the abbreviated 510(k) approval process. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to these pelvic mesh products, including the Advantage Fit pelvic mesh product at issue in this case.

16. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in Plaintiff and others is biologically incompatible with human tissue, and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendant's Pelvic Mesh Products.

17. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response, and chronic pain. It also can cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the mesh. Certain information was available in the medical literature regarding the dangers of polypropylene mesh and manufacturers should have been aware of this literature.

- a. Shrinkage and bacteria lead to an evolving process and increased erosion (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449).
- b. Polypropylene mesh has long been known to shrink (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449). By 1998, polypropylene mesh was known to shrink 30-50%. This was subsequently confirmed in 2007 (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449). Predominate infection/inflammation was noted in 2007 in explanted polypropylene samples (Yahi Y. Int Urogyn J 2007; 18(Suppl 1):S149).
- c. The weave of the mesh produces very small interstices which allow bacteria to enter and to hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing slime (biofilm) which further serves to protect them from destruction by white blood cells and macrophages (Osterberg B. ActaChirScand1979; 145:431, Merritt K. J BiomatAppl 1991; 5:185, An Y. J Biomed Mater Res (ApplBiomat) 1998; 43:338).
- d. The large surface area promotes wicking of fluids and bacteria which provides a safe haven for bacteria which attach themselves to the mesh during the insertion process (Mahmoud W. J Biomat Sci Polymer Ed 1996; 7:751, Klinge U. J Biomed Mater Res 2002; 63:765, Vollebregt A. Int Urogyn J 2009; 20:1345).

- e. The size of the mesh placed equates to a large surface area with many places for bacteria to hide while being protected from host defenses (Mahmoud W. J Biomat Sci Polymer Ed 1996; 7:751, Klinge U. J Biomed Mater Res 2002; 63:765, Vollebregt A. Int Urogyn J 2009; 20:1345).
- f. Polypropylene is impure: There is no such thing as pure polypropylene. Polypropylene contains about 15 additional compounds which are leached from the polypropylene and are toxic to tissue which enhances the inflammatory reaction and the intensity of fibrosis (Sternschuss G. J Urol 2012; May 12 epub, Frostling H. Scand J Work Environ Health 1984; 10:163).
- g. Prolene (polypropylene) was shown to be not inert in 1986 and again in 2003 with flaking and fissuring demonstrated by scanning electron microscopy which leads to degradation and release of toxic compounds. This enhances the inflammatory and fibrotic reactions (Coda A. Hernia 2003; 7:29, Jongebloed WL. Doc Ophthalmol 1986; 64:143–52).
- h. With the loss of polypropylene due to degradation, the surface area is greatly increased thus providing greater areas for bacterial adherence and more elution of toxic compounds from the polypropylene and also the freed toxic polypropylene itself, all of which increases the inflammatory reaction and intensity of fibrosis (Jongebloed W. Doc Ophth 1986; 64:143, Sternschuss G. J Urol 2012; May 12 epub, Clave A. Int Urogyn J 2010; 21:261).

- i. Complications from mesh placement for pelvic organ prolapse include among other adverse events: acute and chronic infection, tissue contraction due to mesh shrinkage, erosion of the mesh into adjacent structures, and dyspareunia [painful sexual intercourse]. Cosson, M., et al., Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material? *Int Urogynecol J Pelvic Floor Dysfunct*, 2003. 14(3): p. 169-78; discussion 178. Jones, K.A., et al., Tensile properties of commonly used prolapse meshes. *Int Urogynecol J Pelvic Floor Dysfunct*, 2009. 20(7): p. 847-53. Margulies, R.U., et al., Complications requiring reoperation following vaginal mesh kit procedures for prolapse. *Am J Obstet Gynecol*, 2008. 199(6): p. 678 e1-4.
- j. Erosion can be defined as the mesh wearing, or slowly grinding through the vaginal wall. This is a serious complication and moreover, there is evidence that meshes shrink in vivo leading to increased stiffness, pain and poor restoration of the normal properties of the vagina. Dora, C.D., et al., Time dependent variations in biomechanical properties of cadaveric fascia, porcine dermis, porcine small intestine submucosa, polypropylene mesh and autologous fascia in the rabbit model: implications for sling surgery. *J Urol*, 2004. 171(5): p. 1970-3.
- k. Larger pores within polypropylene mesh materials, allowing macrophage and leukocyte migration, reduce infection. Birch C, Fynes MM. The role of synthetic and biological prosthesis in reconstructive pelvic floor surgery. *Curr Opin Obstet Gynecol*. 2002; 14:527–595. 22. Govier FE, Kobashi KC,

Kozlowski PM, Kuznetsov DD, Begley SJ, McGonigle KF, et al. High complication rate identified in sacrocolpopexy patients attributed to silicone mesh. J Urol. 2005;65:1099–1103.

18. Defendant used Marlex® HGX-030-01 Polypropylene Homopolymer resin in its transvaginal mesh kits, both pelvic organ prolapse kits and sling systems. The Marlex® resin was manufactured by Phillips Sumika Polypropylene Company, (“Phillips”) a joint venture between Chevron Phillips Chemical Company, LP, and Sumitomo Chemical.

19. Marlex HGX-030-01 resin is a polypropylene plastic that comes in the form of pellets. For several years, Phillips issued revised Material Safety Data Sheets (“MSDS”) for Marlex polypropylene. Defendant was aware of the Marlex MSDS at all relevant times, including when it manufactured and marketed its Products to the public, including Plaintiff and her physicians.

20. The Marlex MSDS expressly prohibits use of the material for permanent human implantation:

MEDICAL APPLICATION CAUTION: DO NOT USE THIS CHEVRON PHILLIPS CHEMICAL MATERIAL IN MEDICAL APPLICATIONS INVOLVING PERMANENT IMPLANTATION IN THE HUMAN BODY OR PERMANENT CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES.

DO NOT USE THIS CHEVRON PHILLIPS CHEMICAL COMPANY LP MATERIAL IN MEDICAL APPLICATIONS INVOLVING BRIEF OR TEMPORARY IMPLANTATION IN THE HUMAN BODY OR CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES UNLESS THE MATERIAL HAS BEEN PROVIDED DIRECTLY FROM CHEVRON PHILLIPS CHEMICAL COMPANY LP UNDER AN AGREEMENT WHICH EXPRESSLY ACKNOWLEDGES THE CONTEMPLATED USE.

CHEVRON PHILLIPS CHEMICAL COMPANY LP MAKES NO REPRESENTATION, PROMISE, EXPRESS WARRANTY OR IMPLIED WARRANTY CONCERNING THE SUITABILITY OF THIS MATERIAL FOR USE IN IMPLANTATION IN THE HUMAN BODY OR IN CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES.

21. When the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue in this case, are inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

22. On October 1, 2004, Phillips Sumika Polypropylene Company (PSPC) entered a one-year stand-alone indemnification/insurance agreement which waived the company's liability for Boston Scientific's decision to use the polypropylene material in medical applications. That agreement included the following language for Boston Scientific's use of the resin material in its transvaginal mesh products:

BEFORE USING ANY PSPC POLYPROPYLENE PRODUCT, BOSTON SCIENTIFIC IS ADVISED AND CAUTIONED TO MAKE ITS OWN DETERMINATION AND ASSESSMENT OF THE SAFETY AND SUITABILITY OF THE PSPC POLYPROPYLENE PRODUCT FOR USE BY, FOR OR ON BEHALF OF BOSTON SCIENTIFIC. IT IS THE ULTIMATE RESPONSIBILITY OF BOSTON SCIENTIFIC TO ENSURE THAT THE PSPC POLYPROPYLENE PRODUCT IS SUITED TO BOSTON SCIENTIFIC'S SPECIFIC APPLICATION.

23. The 2004 Indemnity Agreement placed the burden on Boston Scientific to conduct any and all necessary testing to ensure that the product they marketed with Marlex resin was safe for its intended use.

24. Subsequent to this 2004 indemnity agreement, in September of 2005, Phillips decided not to renew its contract with Boston Scientific because the resin was not intended for use in permanent implant devices. Per the terms of the 2004 contract between the two companies, Boston Scientific decided to exercise a right it held to make a "last-time" buyout before the contract was terminated. In 2005, BSC purchased 4,000 pounds of Marlex® HGX-030-01, the equivalent of a 10-year supply.

25. Synthetic materials like polypropylene, including that used by Defendant, are known to induce an acute inflammatory response, followed by chronic inflammatory response and foreign-body reaction. A chronic inflammatory response and heightened foreign body reaction have the potential to result in failure of the device to perform safely and effectively, with significant adverse consequences for the patient. Further, a prolonged inflammatory response exposes the polypropylene mesh to a continuous bath of oxidants that may cause in vivo degradation of the mesh.

26. The polypropylene MSDS specifies that polypropylene may react with strong oxidizing agents. Despite the known warnings and complications, Defendant utilized Marlex that had never been qualified by the supplier for permanent human implantation for a medical application that was disallowed according to the Material Safety Data Sheet (MSDS) in its manufacture of the Advantage Fit sling.

27. The polypropylene mesh used by Defendant for its Pelvic Mesh Products also contracts as a result of the development of scar tissue exacerbated by the foreign body reaction. Polypropylene mesh is known to shrink by up to over 50% during healing. When the transvaginal mesh shrinks during the normal healing process, the arms of the mesh pull on their anchoring points in the pelvic sidewall muscles, tending to pull these anchoring points and the attached muscle toward the midline. In women with these transvaginal mesh implants, including Plaintiff herein, this pulling on the pelvic sidewall muscles causes pain at rest, during sexual intercourse, during defecation, and during normal daily activities like coughing, jumping and straining. This aggravated pulling will cause new or worsening pain to the women in whom the product is implanted. In addition, it is well established that nerves can become entrapped as a result of the chronic inflammatory response and fibrosis surrounding the mesh.

28. Defendant marketed the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product, to the medical community and to patients as safe, effective, and reliable medical devices that can be implanted by safe, effective, and minimally invasive surgical techniques.

29. Defendant marketed and sold the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product, through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies included, but are not limited to, aggressive marketing and the provision of valuable cash and non-cash benefits to healthcare providers. Defendant also utilized documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of this product.

30. Contrary to the representations and marketing of Defendant, the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product, have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating revision surgeries, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff. The defects stem from many issues, including:

- a. the use of polypropylene material in the Pelvic Mesh Products and the immune reaction that results;
- b. the design of the Pelvic Mesh Products to be inserted transvaginally into an area of the body with high levels of pathogens that adhere to the mesh, which can cause immune reactions and subsequent tissue breakdown;
- c. the contraction or shrinkage of the mesh;
- d. biomechanical issues with the design of the mesh that creates strong amounts of friction between the mesh and the underlying tissue that subsequently causes that tissue to degrade;

- e. the use and design of the Pelvic Mesh Products which, when placed correctly, are likely to pass through and injure major nerve routes in the pelvic region;
- f. degradation of the mesh itself over time which causes the internal tissue to degrade;
- g. the welding of the mesh itself during production, which creates a toxic substance that contributes to the degradation of the mesh and host tissue; and
- h. the design of the Advantage Fit requires penetration into the nerve-rich environment of the pelvic floor, which results frequently in the destruction of nerve endings.

31. Upon information and belief, Defendant has consistently underreported and withheld information about the propensity of its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product, to fail and cause injury and complications, and have misrepresented the efficacy and safety of these products, through various means and media, actively and intentionally misleading the public.

32. Despite the chronic underreporting of adverse events associated with the Pelvic Mesh Products, enough complaints were recorded for the Food and Drug Administration (“FDA”) to issue a public health notification regarding the dangers of these devices. On October 20, 2008, the FDA issued a Public Health Notification that described over a thousand (1,000) complaints (otherwise known as “adverse events”) that had been reported over a three-year period relating to the Pelvic Mesh Products and other similar products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA’s MAUDE database indicates that Defendant is one of the manufacturers of the products that are the subject of the notification.

33. On July 13, 2011, the FDA issued a Safety Communication entitled, “UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic

Organ Prolapse.” Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of pelvic organ prolapse was an area of **“continuing serious concern”** (emphasis added). The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse were “not rare.” These serious complications include, but are not limited to, neuromuscular problems, vaginal scarring/shrinkage, and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization. The FDA concluded that it was not clear that transvaginal repair of pelvic organ prolapse and stress urinary incontinence with mesh-kits was more effective than traditional non-mesh repair of these conditions. The FDA conducted a systematic review of the published scientific literature from 1996 to 2011 and concluded that transvaginal pelvic organ prolapse repair with mesh “does not improve symptomatic results or quality of life over traditional non mesh repair.” In the July 13, 2011, Safety Communication, the FDA concluded that “a mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient’s quality of life. Complete removal of mesh may not be possible.” The information contained in the FDA’s Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011, was known or knowable to Defendant and was not disclosed in any manner.

34. In September 2011, the FDA acknowledged the need for additional data and noted in “Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence” that the literature and information developing on SUI repair with mesh “indicates

that serious complications can occur...[and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI.”

35. After the 2011 FDA notification that mesh complications from POP repairs were “not rare,” a 2013 article was published that stated: “as outlined in the FDA notifications, patients should be forewarned that some transvaginal mesh complications are life altering and might not always be surgically correctable. Furthermore, that study noted that “the women who received both MUS and TM represented a complicated surgical group. Fifteen women (43%) required MUS takedown concurrently with prolapse mesh excision. Two-thirds of these women had associated chronic pelvic pain and vaginal pain, in addition to their urinary symptoms.”

36. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists (ACOG) and the American Urogynecologic Society (AUGS) also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating: There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh...Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

37. Plaintiff’s injuries, as will be more fully established in Discovery, are of the type reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

38. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks. Specifically, the FDA Safety Communication stated: “it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it

may expose patients to greater risk.”

39. Contemporaneously with the Safety Communication, the FDA released a publication titled “Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse” (the White Paper). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that “[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh.”

40. The FDA White Paper further stated that, “these products are associated with serious adverse events...compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair.”

41. In its White Paper, the FDA advises doctors to, inter alia, “[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications.” The FDA concludes its White Paper by stating that it “has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse.”

42. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it “has NOT seen conclusive evidence that using transvaginal placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk.

43. On April 16, 2019, the FDA ordered all manufacturers of surgical mesh intended for transvaginal repair of anterior compartment prolapse (cystocele) to stop selling and distributing their products immediately. In fact, the FDA has determined that the manufacturers, Boston

Scientific and Coloplast specifically, have not demonstrated reasonable assurance of safety and effectiveness for these devices, which is the premarket standard that now applies to them since the agency reclassified them into class III (high risk) in 2016.¹

44. Boston Scientific knew known about the Pelvic Mesh Products' risks and complications identified in the FDA Safety Communication, ACOG/AUGS Joint Committee Opinion, and the FDA Advisory that addressed the sales of transvaginal mesh implants for pelvic organ prolapse.

45. Defendant has further known the following:

- a. that some of the predicate devices for the Pelvic Mesh Products had high failure and complication rates, resulting in the recall of some of these predicate devices;
- b. that there were and are significant differences between the Pelvic Mesh Products and some or all of the predicate devices, rendering them unsuitable for designation as predicate devices;
- c. that these significant differences render the disclosures to the FDA incomplete and misleading; and
- d. that the Pelvic Mesh Product was and is causing numerous patients' severe injuries and complications.

46. Defendant suppressed this information and failed to accurately and completely disseminate or share this and other critical information with others, including Plaintiff. As a result, Defendant actively and intentionally misled and continues to mislead the public into believing that

¹ www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants (last visited 10/14/2021).

the Pelvic Mesh Products and the procedures for implantation were and are safe and effective.

47. Defendant failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Pelvic Mesh Products. Defendant did not, and has not, adequately studied the extent of the risks associated with its Pelvic Mesh Products.

48. The Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to Defendant, as it generated the directions for use, created the procedures for implanting the device, and trained the implanting physicians.

49. Defendant provided incomplete, insufficient, and misleading training and information to physicians to increase the number of physicians utilizing the Pelvic Mesh Products, and thus increase the sales of these products.

50. The injuries, conditions, and complications suffered by women who have been implanted with the Pelvic Mesh Products include, but are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, acute and chronic nerve damage and pain, obturator nerve damage/neuralgia, pudendal nerve damage/neuralgia, ilioinguinal nerve damage/neuralgia, pelvic floor damage, myofascial pain, chronic pelvic pain, urinary and fecal incontinence, and prolapse of organs. In many cases, these women have been forced to undergo intensive medical treatment, including, but not limited to, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and surgeries to remove portions of the female genitalia, to locate and remove mesh, and to attempt to repair pelvic organs, tissue, and nerve damage.

51. The medical and scientific literature studying the effects of polypropylene pelvic mesh (like the material used in the Pelvic Mesh Products) have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

52. Defendant knew and had reason to know that the Pelvic Mesh Products could and would cause severe and grievous personal injury to the users of the Pelvic Mesh Products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

53. At all relevant times herein, Defendant continued to promote the Pelvic Mesh Products as safe and effective even when no clinical trials had been done supporting long or short-term efficacy.

Defective Design

54. The Advantage Fit is designed to be inserted into the levator muscles of the pelvic floor, producing a foreseeable risk of acute and chronic myofascial pain as well as a foreseeable risk of ilioinguinal, pudendal, and obturator neuralgia. Defendant failed to study or account for anatomic variations of these nerves when designing the device.

55. The Pelvic Mesh Products were designed to be permanently implanted into a woman's body yet the product changes after implantation; it contracts over time which can pull or compress nerves important for sexual function, mobility, bowel function, bladder function, and chronic pelvic and nerve pain (neuralgia). This contraction over time, which can pull, and also cause fibrosis of muscles, muscle spasms, adhesions between tissues, and inflammation which impair sexual function, impaired mobility, impaired bowel and bladder function, and chronic

pelvic pain, neuralgia, among other mesh-related issues.

56. Moreover, despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in Plaintiff is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendant's Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue herein. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, causes chronic inflammation of the pelvic tissue, causes shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain, cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the polypropylene mesh.

57. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction."

58. Defendant's Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue, were and are unreasonably susceptible to degradation and fragmentation inside the body, shrinkage or contraction inside the body, intense foreign body reaction, chronic inflammatory response, chronic wound healing, chronic infections in and around the mesh fibers,

and nerve entrapment in the collagen scar formation. Defendant knew or should have known of these serious risks and should have, therefore, warned physicians and patients regarding these risks to the extent they were known or knowable.

59. To this day, the Advantage Fit pelvic mesh product continues to be marketed to the medical community and to patients as safe, effective, and reliable medical devices, implanted by safe, effective, and minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments and other competing products.

60. Defendant knew or should have known that its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue in this case, unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks. At the time Defendant began marketing the Advantage Fit, Defendant was aware that the Advantage Fit was associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011, safety communication.

61. Defendant omitted and downplayed the risks, dangers, defects, and disadvantages of its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue, and advertised, promoted, marketed, sold and distributed the its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue, as safe medical devices when Defendant knew or should have known that the Pelvic Mesh Products were not safe for their intended purposes, and that the products would cause, and did cause, serious medical problems, and in many patients, including Plaintiff, catastrophic injuries. Further, while some of the problems associated with the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product, were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden

from physicians.

62. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue, have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making them defective under the law.

63. Further, Defendant failed to design and establish a safe, effective procedure for removal of its Pelvic Mesh Products, including the Advantage Fit pelvic mesh products at issue, or to determine if a safe, effective procedure for removal of the Pelvic Mesh Products exists. Thus, in the event of a failure, injury, or complications, it is impossible to easily and safely remove the Pelvic Mesh Products.

64. Feasible, suitable, and safer alternative designs to Defendant's Advantage Fit pelvic mesh products, have existed at all times relevant and in reasonable probability would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the products' utility. These safer alternative designs were economically and technologically feasible at the time the Pelvic Mesh Products left the control of Defendant by the application of existing or reasonably achievable scientific knowledge. Safer alternatives designs for the Advantage Fit included but were not limited to: the Burch Procedure colposuspension with delayed absorbable sutures; autologous fascia slings; an allograft sling using a product like Boston Scientific's Repliform® or other biological matrix; a sling with less polypropylene such as Ultrapro; a sling made with DynaMesh or other Polyvinylidene fluoride (PVDF) alternative, a

retropubic mini-sling, such as the TFS device from TFS Surgical, a retropubic sling comprised of Dynamesh or other PVDF alternative, or a retropubic mini-sling comprised of DynaMesh or other PVDF alternative.

65. The specific nature of defects for Defendant's Advantage Fit pelvic mesh product at issue in this case include, but are not limited to, the following:

- A. The use of polypropylene in the Pelvic Mesh Products and the adverse tissue reactions and host defense response that result from such material, causing adverse reactions and serious, permanent injuries including, but not limited to, painful recurrent erosions and associated intractable pain;
- B. The design of the Advantage Fit to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic infections, subclinical infections and biofilms, enhanced chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries;
- C. The use and design of the Advantage Fit sling, which, when placed in the women, is likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;
- D. The procedure to place the Advantage Fit sling requires penetration of the levator muscles of the pelvic floor, which can injure major nerves that contribute to sexual function, contribute to mobility, and contribute to bowel and bladder function;

- E. Biomechanical issues with the design of the Advantage Fit which results in a non-anatomic condition leading to contraction or shrinkage of the mesh inside the body, that in turn causes surrounding tissue to become eroded, inflamed, fibrotic and infected, resulting in serious and permanent injury;
- F. The propensity of the mesh design characteristics of the Advantage Fit mesh for plastic deformation when subjected to tension both during implantation and once implanted inside the body which causes the mesh, or portions thereof, to be encapsulated in a rigid scar plate which leads to nerve entrapment, bacterial entrapment, tissue destruction, enhanced inflammatory and fibrotic response and chronic pain;
- G. The propensity of the mesh used in the Advantage Fit mesh to become rigid and inflexible, causing it to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where the product is implanted, and causing discomfort and pain with normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);
- H. The propensity of the mesh used in the Advantage Fit for degradation or fragmentation over time, which causes an increased surface area that leads to enhanced chronic inflammatory and fibrotic reaction, causes a “barbed wire” or “saw blade” effect by the fragmented surface “sawing” through the tissue, leads to bacteria harboring in the fragmented, peeled and split fiber surface which in turn leads to chronic infections at the mesh surface, and results in continuing injury over time; and
- I. The inability of surgeons to effectively treat many of these conditions due to the integration of the mesh into the pelvic tissue and thus the inability to safely remove or

excise the mesh once a complication occurs.

Failure to Warn/Inadequate Warnings & Instructions

66. At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put the Plaintiff, her treating physicians, and the public on notice of the dangers and adverse effects caused by implantation of the Pelvic Mesh Products.

67. The Advantage Fit is also defective due to Defendant's failure to adequately warn or instruct Plaintiff and/or her health care providers after the product left the manufacturer and before and after implantation of the Advantage Fit pelvic mesh product of subjects including, but not limited to, the following:

- A. The Pelvic Mesh Products' propensities, including the Advantage Fit product, to contract, retract, and/or shrink inside the body;
- B. The Pelvic Mesh Products' propensities, including the Advantage Fit product, for degradation, fragmentation and/or migration;
- C. The Pelvic Mesh Products', including the Advantage Fit product, inelasticity preventing proper mating with the pelvic floor and vaginal region;
- D. The frequency and manner of transvaginal mesh erosion or extrusion resulting from the Pelvic Mesh Products, including the Advantage Fit product;
- E. The risk of chronic inflammation resulting from the Pelvic Mesh Products, including the Advantage Fit product;
- F. The risk of chronic infections resulting from the Pelvic Mesh Products, including the Advantage Fit product;

- G. The risk of permanent vaginal or pelvic scarring resulting from the Pelvic Mesh Products, including the Advantage Fit product;
- H. The risk of de novo urinary dysfunction resulting from the Pelvic Mesh Products, including the Advantage Fit product;
- I. The risk of de novo dyspareunia or painful sexual intercourse resulting from the Pelvic Mesh Products, including the Advantage Fit product;
- J. The risk of recurrent, intractable pelvic pain and other pain resulting from the Pelvic Mesh Products, including the Advantage Fit product;
- K. The risk of obturator nerve irritation/obturator neuralgia resulting from the Pelvic Mesh Products, including the Advantage Fit product;
- L. The risk of pudendal nerve irritation/pudendal neuralgia resulting from the Pelvic Mesh Products, including the Advantage Fit product;
- M. The risk of ilioinguinal nerve irritation/ilioinguinal neuralgia resulting from the Pelvic Mesh Products, including the Advantage Fit product;
- N. The need for corrective or revision surgery to adjust or remove the Pelvic Mesh Products, including the Advantage Fit product, which in some cases is not feasible nor possible;
- O. The severity of complications that could arise as a result of implantation of the Pelvic Mesh Products, including the Advantage Fit product;
- P. Treatment of stress urinary incontinence with Defendant's Advantage Fit Pelvic Mesh Product is no more effective than feasible, available and safer alternatives;
- Q. Treatment of stress urinary incontinence with Defendant's Advantage Fit Pelvic Mesh

- Product exposes patients to greater risk than feasible, available and safer alternatives;
- R. Treatment of stress urinary incontinence with the Advantage Fit Pelvic Mesh Product makes future surgical repair more difficult than feasible, available and safer alternatives;
- S. Use of the Pelvic Mesh Products, including the Advantage Fit product, puts the patient at greater risk of requiring additional surgery than feasible, available and safer alternatives;
- T. Removal of the Pelvic Mesh Products, including the Advantage Fit product, due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;
- U. Complete removal of the Pelvic Mesh Products, including the Advantage Fit product, may not be possible and may not result in complete resolution of the complications, including pain; and
- V. The nature, magnitude, and frequency of the complications that could arise as a result of implantation of the Pelvic Mesh Products, including the Advantage Fit product.
- W. The Pelvic Mesh Products' defects and hazards described herein;

68. Defendant underreported and continues to underreport information about the propensity of its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue, to fail and cause injury and complications and have made unfounded representations regarding the efficacy and safety of the Pelvic Mesh Products through various means and media.

69. Defendant underreported and continues to underreport information about the propensity of its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue,

to fail and to cause injury and complications and have made unfounded representations regarding the efficacy and safety of its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue, through various means and media.

70. Defendant failed to perform proper and adequate testing and research in order to determine and evaluate the nature, magnitude and frequency of the risks attendant to its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue.

71. The Advantage Fit pelvic mesh product at issue was at all times utilized and implanted in a manner intended and/or foreseeable to Defendant, as Defendant generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physician.

72. Defendant knowingly provided incomplete and insufficient training and information to physicians regarding the use of its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue, and the aftercare of patients implanted with those Pelvic Mesh Products.

73. At all relevant times herein, Defendant continued to promote its products as safe and effective even when no clinical trials had been done supporting long-term or short-term efficacy or safety. In doing so, Defendant failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with its Pelvic Mesh Products, including the magnitude and frequency of these risks.

74. At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put Plaintiff, the medical community, Plaintiff's treating physicians, and the general public on notice of the dangers and adverse effects caused by implantation of the

Defendant's Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue.

75. Defendant's Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue, as designed, manufactured, distributed, sold and/or supplied by Defendant, were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendant's knowledge of lack of safety.

76. The risk of serious injuries was known or should have been known to Defendant, but in spite of these risks, Defendant continued to market the Advantage Fit pelvic mesh product for transvaginal use to physicians and patients, including Plaintiff and Plaintiff's healthcare providers, without adequate warnings.

Resulting Injury from Defendant's Pelvic Mesh Products

77. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with Defendant's Pelvic Mesh Products include, but are not limited to: erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, obturator nerve damage/neuralgia, pudendal nerve damage/neuralgia, ilioinguinal nerve damage/neuralgia, pelvic floor damage, chronic pelvic pain, emotional distress and mental anguish, and other debilitating complications. In addition, affected women, including Plaintiff, will need to be continuously monitored because of being implanted with Defendant's Pelvic Mesh Products.

78. In many of these cases, including that of the Plaintiff, women have had or will have to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of

pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia. Removal of contracted, eroded and/or infected transvaginal mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

79. The medical and scientific literature studying the effects of pelvic mesh products, like that of the Advantage Fit pelvic mesh product implanted in Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the pelvic mesh products.

Plaintiff's Advantage Fit Implantation

80. Upon information and belief, Dr. Scott L. Sinnott, M.D. recommended the Advantage Fit pelvic mesh product to Plaintiff as appropriate and safe for the treatment of her stress urinary incontinence. Consequently, Plaintiff consented to the implantation of the Advantage Fit pelvic mesh product.

81. On or about September 19, 2012, Plaintiff underwent surgery to address her stress urinary incontinence with Dr. Scott L. Sinnott, M.D. at Franciscan St. Elizabeth Health in Lafayette, Indiana. During this surgery, she was implanted with both a Boston Scientific Advantage Fit sling, identified as follows:

PROCEDURE IMPLANTS			
OR DESCRIPTION:	IMPL SLING ADVANTAGE FIT MID URETHRAL	QTY:	1
SERIAL #:		MODEL #:	
LOT #:	ML00000754	CATALOG:	M0068502110
SIZE:		SITE:	OPERATIVE SITE
MANUFACTURER:	BOSTON SCIENTIFIC CORP	DEVICE TYPE:	OTHER
COMMENT:			

82. The Advantage Fit pelvic mesh product implanted in Plaintiff was in the same or substantially similar condition as it was when it left Defendant's possession, and in the condition

directed by and expected by Defendant.

83. Plaintiff and her physician foreseeably used and implanted the Advantage Fit pelvic mesh product properly and appropriately and did not misuse or alter these products in an unforeseeable manner.

84. Neither Plaintiff nor her healthcare providers were warned that the Advantage Fit pelvic mesh product was unreasonably dangerous or of the risks of the Pelvic Mesh Products, outlined herein, even when used exactly as intended by Defendant. To the contrary, Defendant promoted and sold the type of transvaginal mesh devices implanted in Plaintiff and thousands of women like Plaintiff, to healthcare providers as a safe alternative to other procedures that did not incorporate the Defendant's products.

85. On information and belief, Plaintiff's implanting physician would have advised Plaintiff of the risks of the device included in the Advantage Fit IFU, and considered these risks in the risk-benefit analysis.

86. As a direct and proximate cause of having the Advantage Fit pelvic mesh device implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, including obturator neuralgia, pudendal neuralgia, ilioinguinal neuralgia, dyspareunia, neuromuscular pain, disabling pelvic pain, abdominal pain, infections, prolapse and incontinence, urinary problems, and vaginal scarring, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

87. As a direct and proximate result of being surgically implanted with Defendant's unreasonably dangerous Advantage Fit pelvic mesh product, Plaintiff has suffered, and continues to suffer, debilitating injuries, including but not limited to the injuries listed above and, likely, nerve pain that may be permanent. Plaintiff brings this suit for damages related to those injuries.

DISCOVERY RULE AND TOLLING

88. Plaintiff realleges and incorporates by reference paragraphs 1 through 86 of this Complaint as if each were set forth fully and completely herein.

89. To the extent further pleading be necessary, Plaintiff asserts all applicable contractual, state statutory and/or common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

90. Plaintiff could not have reasonably discovered her injuries and/or the occasion, manner and/or means by which Defendant's breach of duty occurred until within three years of the filing of this complaint. Further, Plaintiff did not and, exercising reasonable diligence, including consultation with medical professionals, could not discover the existence of her legal cause of action or the injuries caused by Defendant's breach of duty and/or defective products until within three years of the filing of this complaint.

91. Moreover, Defendant continues to deny that its products are defective or cause injuries such as those suffered by Plaintiff and Defendant continued to manufacture and sell the products at issue and/or related or predicate products. Any applicable statute of limitations has been tolled due to equitable tolling by the knowing and active concealment, affirmative misrepresentations, and denial of material facts known by Defendant when Defendant had a duty

to disclose and/or by the application of the discovery rule. As a result of Defendant's fraudulent concealment, Plaintiff and her healthcare providers were unaware, and could not have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of Defendant.

FIRST CAUSE OF ACTION
[Negligence]

92. Plaintiff realleges and incorporates by reference paragraphs 1-90 of this Complaint as if each were set forth fully and completely herein.

93. At all times herein mentioned, Defendant was engaged in the business of researching, manufacturing, licensing, fabricating, designing, labeling, distributing, using, supplying, selling, marketing, warranting, packaging and advertising the Advantage Fit pelvic mesh product at issue in this case.

94. Defendant owed to Plaintiff and the public a duty to act reasonably and to exercise ordinary care in pursuit of the activities mentioned above, and Defendant breached said duty of care.

95. At all times relevant hereto, Defendant owed to Plaintiff and the public a duty to act reasonably and to exercise ordinary care with respect to the safe, legal, and proper manufacture, license, design, formulation, distribution, production, processing, assembly, testing, inspection, research, marketing, labeling, packaging, preparation for use, issuance of warnings with respect to use, promotion, advertising, sale, and safety monitoring of the Advantage Fit pelvic mesh product, and to adequately test and warn of the risk and dangers of the Advantage Fit pelvic mesh product, both before and after sale.

96. Further, Defendant owed to Plaintiff and the public a duty to act reasonable and to exercise ordinary care in the education and training of physicians regarding the risks, benefits, and implantation of its Pelvic Mesh Products.

97. Additionally, Defendant owed to Plaintiff and the public a duty to provide accurate, reliable, and completely truthful information regarding the safety and any dangerous propensities of the Advantage Fit manufactured, used, distributed, and/or supplied by them and to provide accurate, reliable, and completely truthful information regarding the failure of the Advantage Fit pelvic mesh product to perform as intended or as an ordinary consumer would expect.

98. Defendant further breached its duty of care in the testing of its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue in this case, by failing to conduct adequate testing to ensure that the Pelvic Mesh Products were reasonably safe for implantation in the female pelvic area prior to releasing the Pelvic Mesh Products into the market, failing to conduct post-launch testing following adverse findings in the scientific and medical literature, and by failing to conduct post-launch testing to investigate and evaluate reports in the FDA adverse event databases for their potential significance for Defendant's Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue in this case.

99. Defendant breached the duty to take all reasonable steps necessary to manufacture and sell products that were not defective or unreasonably dangerous to consumers and users of the products, including Plaintiff herein. Defendant was negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Pelvic Mesh Products at issue herein. Defendant breached the aforementioned duties in that Defendant negligently and carelessly designed, licensed, inspected or failed to inspect, tested or

failed to test, inadequately warned or failed to warn of the health hazards, labeled, distributed, handled, used, supplied, sold, marketed, warranted, packaged, promoted, and advertised the Advantage Fit pelvic mesh product in that said Advantage Fit pelvic mesh product caused, directly and proximately, the injuries of Plaintiff through failure of the Advantage Fit pelvic mesh product to perform as intended or as an ordinary consumer would expect. Defendant breached the aforementioned duty by, among other things:

- a. Failing to design the Pelvic Mesh Products at issue herein so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Products at issue herein was implanted, including Plaintiff;
- b. Failing to manufacture the Pelvic Mesh Products at issue herein so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Products at issue herein were implanted, including Plaintiff;
- c. Failing to use reasonable care in the testing of the Pelvic Mesh Products at issue herein so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Products at issue herein was implanted, including Plaintiff;
- d. Failing to use reasonable care in inspecting the Pelvic Mesh Products at issue herein so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Products at issue herein was implanted, including Plaintiff;
- e. Failing to use reasonable care in the training and instruction to physicians for the safe use of the Pelvic Mesh Products at issue herein;
- f. Failing to use reasonable care in studying the Pelvic Mesh Products at issue herein to evaluate its safety and to determine the nature, magnitude, and

frequency of serious, life threatening complications that were known or knowable; and

- g. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Pelvic Mesh Products at issue herein.

100. Defendant also negligently failed to warn, train, and instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

- a. The use of polypropylene and/or collagen material in the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue herein, and the immune reaction that results from such material, causing adverse reactions and injuries;
- b. The design of the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue herein, to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;
- c. Biomechanical issues with the design of the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue herein, including, but not limited to, the propensity of the Pelvic Mesh Products at issue herein to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;
- d. The use and design of the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue herein, which, when placed in women, such

as Plaintiff, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

- e. The propensity of the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue herein, for “creep,” or to gradually elongate and deform when subjected to prolonged tension inside the body;
- f. The inelasticity of the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue herein, causing it to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);
- g. The propensity of the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue herein, for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;
- h. The hyper-inflammatory responses to the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue herein, leading to problems including chronic pain and fibrotic reaction;
- i. The propensity of the mesh material in the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue herein, to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;
- j. The adverse tissue reactions caused by the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue herein, which are causally

related to infection, as the polypropylene is a foreign material; and

- k. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions.

101. Defendant also negligently failed to warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

- a. The Pelvic Mesh Products' propensities to contract, retract, and/or shrink inside the body;
- b. The Pelvic Mesh Products' propensities for degradation, fragmentation and/or creep;
- c. The Pelvic Mesh Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;
- d. The rate and manner of mesh erosion or extrusion;
- e. The risk of chronic inflammation resulting from the Pelvic Mesh Products at issue herein;
- f. The risk of chronic infections resulting from the Pelvic Mesh Products at issue herein;
- g. The risk of permanent vaginal or pelvic scarring as a result of the Pelvic Mesh Products at issue herein;
- h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Pelvic Mesh Products at issue herein;
- i. The need for corrective or revision surgery to adjust or remove the Pelvic Mesh Products at issue herein;
- j. The severity of complications that could arise as a result of implantation of the Pelvic Mesh Products at issue herein including permanent nerve damage, neuromuscular problems, obturator nerve irritation/neuralgia, pudendal nerve irritation/neuralgia, and ilioinguinal nerve irritation/neuralgia;

- k. Treatment of stress urinary incontinence with the Pelvic Mesh Products at issue herein is no more effective than feasible available alternatives;
- l. Treatment of stress urinary incontinence with the Pelvic Mesh Products at issue herein exposes patients to greater risk than feasible available alternatives;
- m. Treatment of stress urinary incontinence with the Pelvic Mesh Products at issue herein makes future surgical repair more difficult than feasible available alternatives;
- n. Use of the Pelvic Mesh Products at issue herein puts the patient at greater risk of requiring additional surgery than feasible available alternatives;
- o. Removal of the Pelvic Mesh Products at issue herein due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;
- p. Complete removal of the Pelvic Mesh Products at issue herein may not be possible and may not result in complete resolution of the complications, including pain; and
- q. The Pelvic Mesh Products' defects and hazards described herein.

102. As a proximate result of Defendant's negligent design, marketing, physician training, and testing of its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue in this case, Plaintiff has been injured catastrophically, sustained severe and permanent pain, suffering, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, loss of enjoyment of life, and economic damages.

103. By reason of the foregoing, Plaintiff has sustained damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

104. WHEREFORE, Plaintiff demands judgment against Defendant for compensatory damages, for punitive damages, and for costs in excess of \$75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

SECOND CAUSE OF ACTION
[STRICT LIABILITY - DEFECTIVE DESIGN]
(Ind. Code § 34-20-4, et. seq.)

105. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

106. Additionally, or in the alternative, if same be necessary, Plaintiff re- alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

107. Defendant was and is engaged in the business of selling its pelvic mesh products, including the Advantage Fit pelvic mesh product, in the State of Indiana.

108. Defendant is a manufacturer and/or supplier of Pelvic Mesh Products, specifically the Advantage Fit pelvic mesh product at issue herein, and is strictly liable to Plaintiff for designing, creating, manufacturing, distributing, selling and placing its Pelvic Mesh Products, specifically the Advantage Fit pelvic mesh product, into the stream of commerce.

109. The pelvic mesh product at issue herein, the Advantage Fit device, was designed, marketed, manufactured and distributed by the Defendant and was defective and not reasonably safe due to its improper, inadequate, and defective design.

110. The Advantage Fit pelvic mesh product manufactured, designed, marketed, promoted, and sold by Defendant was expected to, and did, reach Plaintiff without substantial change in the condition in which it was sold and in the condition directed by and expected by Defendant. The Advantage Fit pelvic mesh product was defective at the time of manufacture, development, design, production, testing, inspection, endorsement, prescription, sale and distribution, and at the time it left the possession of the Defendant.

111. Defendant designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue herein, and Plaintiff was an expected user or consumer of the Pelvic Mesh Products.

112. Defendant's Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue in this case, were defectively and improperly designed, rendering the products deficient and unreasonably dangerous and hazardous to Plaintiff.

113. The Pelvic Mesh Products at issue herein that were implanted in Plaintiff were conveyed in a condition not contemplated by reasonable persons among those considered expected users or consumers of the Pelvic Mesh Products, like Plaintiff.

114. Defendant's Pelvic Mesh Products, specifically the Advantage Fit pelvic mesh product, manufactured and/or supplied by Defendant, were defective in design or formulation in that, when they left the hands of Defendant, and they were unreasonably dangerous, taking into consideration the expectations of a reasonable consumer under the circumstances.

115. The Advantage Fit pelvic mesh product at issue herein that was implanted in Plaintiff was, at the time conveyed, not in conformity with the generally recognized state of the art applicable to the safety of the products at the time the products were designed, manufactured, packaged, labeled and/or sold. There were also safer alternative designs for the Advantage Fit device.

116. The Advantage Fit pelvic mesh product at issue herein that was implanted in Plaintiff were not reasonably safe for its intended uses and was defective as described herein with respect to its design. These design defects include, but are not limited to, the following:

- a. The use of polypropylene in the Advantage Fit pelvic mesh product and the foreseeable adverse tissue reactions, host defense response, and immune reactions that result from such material leading to ongoing degradation of the mesh, shrinkage, perpetual scarification as the mesh degrades all of which have potential to produce adverse reactions and permanent injuries including but not limited to painful recurrent erosions, direct muscle and soft tissue injury, nerve entrapment or irritation of adjacent nerves, and associated intractable neuropathic pain and myofascial pain;
- b. The design of the Advantage Fit pelvic mesh product to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic infections, subclinical infections and biofilms, enhanced chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries without producing any additional therapeutic benefit when compared to other surgical treatment options for SUI;
- d. The design of the Advantage Fit to be inserted into and through the levator muscles of the pelvic floor produces a foreseeable risk of ilioinguinal, obturator, and pudendal neuralgia that may present acutely or months to years after implantation;

- f. The design of the Advantage Fit to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries without producing any additional therapeutic benefit when compared to other surgical treatment options for SUI;
- g. Biomechanical issues with the design of the Advantage Fit, including, but not limited to, the propensity of the mesh in the Advantage Fit pelvic mesh product to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in serious and permanent injury to the soft tissues and muscles of the pelvic floor without producing any additional therapeutic benefit when compared to other surgical treatment options for SUI;
- h. The use and design of an introducer and anchors in the Advantage Fit device at issue herein, which, when placed in women, such as Plaintiff, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;
- i. The propensity of the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue herein, for “creep,” or to gradually elongate and deform when subject to prolonged tension inside the body;
- j. The inelasticity of the Advantage Fit pelvic mesh product, causing the product to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g. intercourse,

defecation, or walking) without providing any additional therapeutic benefit when compared to other surgical treatment options for SUI:

- k. The propensity of the mesh in the Advantage Fit pelvic mesh product to degrade or fragment over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time; and
- l. The propensity of the mesh in the Advantage Fit pelvic mesh product to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;
- m. The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;
- n. The hardening of the Advantage Fit pelvic mesh product in the body;
- o. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions that are unique to polypropylene without providing any additional therapeutic benefit when compared to other non-polypropylene surgical treatment options for SUI;
- p. The use of polypropylene material in the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue herein, and the failure to provide adequate directions for use ("DFU") or instructions for use ("IFU") and training.

117. As designed, Defendant's Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue in this case, were and are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the

expectations of patients and their healthcare providers.

118. Defendant's Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue in this case, are not reasonably safe and so likely to be harmful to users that a reasonable person who had actual knowledge of their potential for producing injury would conclude that it should not have been marketed.

119. Defendant's Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue in this case, are dangerous beyond that which would be contemplated by an ordinary person, doctor, or patient with the ordinary knowledge common to the community as to its characteristics.

120. Defendant has intentionally and recklessly designed, marketed, labeled, sold, and distributed its Pelvic Mesh Products (including the Advantage Fit pelvic mesh products at issue in this case) with wanton and willful disregard for the rights and health of Plaintiff, and with malice, placing its economic interests above the health and safety of Plaintiff.

121. At all relevant times, feasible, safer mesh-related alternative designs to the Advantage Fit pelvic mesh product existed, such the Burch Procedure colposuspension with delayed absorbable sutures; autologous fascia slings; an allograft sling using a product like Boston Scientific's Repliform® or other biological matrix; a sling with less polypropylene such as Ultrapro; a sling made with DynaMesh or other Polyvinylidene fluoride (PVDF) alternative, a retropubic mini-sling, such as the TFS device from TFS Surgical, a retropubic sling comprised of Dynamesh or other PVDF alternative, or a retropubic mini-sling comprised of DynaMesh or other PVDF alternative.

122. With respect to Plaintiff in particular, flaws with the Advantage Fit pelvic mesh product's design, including but not limited to the use of polypropylene mesh in the Advantage Fit pelvic mesh product, the weight and pore size of the polypropylene mesh used in the Advantage Fit pelvic mesh product, and the implantation design of the Advantage Fit device, caused and created chronic inflammation and chronic foreign body reaction inside of Plaintiff, as well entrapment, aggravation, irritation and/or compression of Plaintiff's obturator and/or pudendal nerves, which in turn damaged and aggravated the surrounding soft tissues. As a direct and proximate result of these design flaws, Plaintiff has suffered and in all reasonable probability will continue to suffer from dyspareunia, neuromuscular pain, spastic pelvic floor syndrome, pelvic pain, extrapelvic pain, groin pain, vaginal pain, thigh pain, perineal pain, paresthesia, depression, and impaired bladder function, as well as other symptoms and damages, including severe and permanent pain, suffering, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, loss of enjoyment of life, and economic damages.

123. As a direct and proximate result of the wrongful acts and omissions of Defendant, Plaintiff suffered severe injuries, emotional distress, and economic damages for which she now seeks compensation.

124. By reason of the foregoing, Plaintiff has sustained damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

125. WHEREFORE, Plaintiff demands judgment against Defendant for compensatory damages, for punitive damages, and for costs in excess of \$75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

THIRD CAUSE OF ACTION
[STRICT LIABILITY-FAILURE TO WARN]
(Ind. Code § 34-20-4-2, et. seq.)

126. Plaintiff realleges and incorporates by reference paragraphs 1-125 of this Complaint as if each were set forth fully and completely herein.

127. Defendant supplied the Advantage Fit pelvic mesh product that was implanted in Plaintiff.

128. Defendant designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Advantage Fit pelvic mesh product at issue herein.

129. The Advantage Fit pelvic mesh product was manufactured, designed, marketed, labeled and sold in a defective condition, for use by the Plaintiff's physicians and/or healthcare providers and all other consumers of the products, making the products unreasonably dangerous.

130. Defendant's Advantage Fit pelvic mesh product is defective due to Defendant's failure to adequately warn or instruct Plaintiff and/or her health care providers of subjects.

131. In their DFUs, as well as the marketing materials they prepared and disseminated to patients and healthcare providers, Defendant omitted critical information regarding the risks and potential complications of the Advantage Fit pelvic mesh product at issue in this case. Specifically, Defendant failed to properly and adequately warn and instruct Plaintiff and her healthcare providers as to the following (subsequently referred to as the "Risks and Potential Complications"):

- a. That the Advantage Fit pelvic mesh product was not studied prior to launch for safety and efficacy;

- b. That the Advantage Fit pelvic mesh product has propensities to contract, retract, and/or shrink inside the body;
- c. That the Advantage Fit pelvic mesh product has propensities for degradation, fragmentation, and/or creep;
- d. That the Advantage Fit pelvic mesh product's inelasticity prevents proper mating with the pelvic floor and vaginal region;
- e. The magnitude of the risk of mesh erosion or extrusion;
- f. The risk of chronic inflammation resulting from the Advantage Fit pelvic mesh product;
- g. The risk of chronic infections resulting from the Advantage Fit pelvic mesh product;
- h. The risk of developing Chronic Regional Pain Syndrome (Type II) as a result of chronic inflammation/infection;
- i. The risk of permanent vaginal or pelvic scarring as a result of the Advantage Fit pelvic mesh product;
- j. The risk of recurrent, intractable pelvic/extrapelvic pain, nerve pain, and other pain resulting from the Advantage Fit pelvic mesh product;
- k. The risk of secondary nerve injury to the obturator nerve;
- l. The risk of acute nerve irritation to the pudendal nerve;
- m. The risk of secondary nerve irritation to the pudendal nerve;
- n. The risk of acute nerve irritation to the ilioinguinal nerve;
- o. The risk of secondary nerve irritation to the ilioinguinal nerve;
- p. The magnitude of the risk of dyspareunia (painful sexual intercourse) in patients;

- q. That the Advantage Fit pelvic mesh product may result in dyspareunia that makes vaginal penetration impossible;
- r. The frequency with which the need for corrective or revision surgery to adjust or remove the Advantage Fit pelvic mesh products may occur in patients;
- s. The magnitude of the risk of acute and long-term complications that could arise as a result of implantation of the Advantage Fit pelvic mesh product in patients;
- t. The hazards associated with the Advantage Fit pelvic mesh product, including obturator, pudendal neuralgia, and ilioinguinal neuralgia, permanent nerve damage, and pelvic floor and groin myalgia;
- u. That treatment of SUI with the Advantage Fit pelvic mesh product exposes patients to greater risk than feasible available devices for SUI, including retropubic mini-slings and pelvic mesh products utilizing alternative polypropylene material or non-polypropylene surgical products, alternatives, and procedures;
- v. That treatment with the Advantage Fit pelvic mesh product makes future surgical repair more difficult than feasible available alternatives;
- w. That the Advantage Fit pelvic mesh product offers no improvement in efficacy compared to non-mesh repairs and non-mesh repairs do not place the obturator or pudendal nerve at risk acutely or over time;
- x. That use of the Advantage Fit pelvic mesh product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;
- y. That removal of the Advantage Fit pelvic mesh product due to complications may significantly impair the patient's quality of life;

- z. That complete removal of the Advantage Fit pelvic mesh product may not be possible;
- aa. That complete removal of the Advantage Fit pelvic mesh product may not result in complete resolution of the complications, including pain;
- bb. The foreseeable and unavoidable risk of acute ilioinguinal and/or pudendal neuralgia and/or ilioinguinal, obturator, and pudendal neuralgia occurring months or years after implantation;
- cc. The magnitude of the risk of obturator, ilioinguinal and/or pudendal neuralgia; and
- dd. The risk of permanent injury and pain to the muscles and soft tissues of the pelvic floor that may occur acutely after implantation or become symptomatic months or years after implantation.

132. Arguing further, Defendant failed to properly and adequately warn and instruct Plaintiff and her healthcare providers as to the proper candidates for, and the safest and most effective methods of, implantation and use of Defendant's Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue in this case. Defendant also failed to properly and adequately warn and instruct Plaintiff and her healthcare providers regarding the inadequate research and testing of the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue in this case, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products. Defendant intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of Defendant's Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue in this case, understating the risks and exaggerating the benefits in order to advance its own financial interests, with wanton and willful disregard for Plaintiff's rights and health.

133. Had Defendant properly and adequately warned and instructed Plaintiff and her healthcare providers with regarding to the Advantage Fit pelvic mesh products' Risks and Potential Complications, upon information and belief, Plaintiff would not have been recommended implantation of the Advantage Fit pelvic mesh product, and Plaintiff would not have proceeded with implantation of the Advantage Fit pelvic mesh product, thus avoiding the injuries Plaintiff has alleged herein.

134. As a proximate result of Defendant's design, manufacture, labeling, marketing, sale, and distribution of the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue in this case, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, loss of enjoyment of life, and economic damages.

135. Defendant, by exercising reasonable diligence, could have made such warnings available to Plaintiff, Plaintiff's healthcare providers, and the medical community.

136. As a direct and proximate result of Defendant's failure to provide Plaintiff, Plaintiff's healthcare providers, and the medical community with sufficient or adequate warnings, Plaintiff and Plaintiff's healthcare providers were not adequately informed of the potential dangers and/or defects of the Advantage Fit pelvic mesh product at issue herein.

137. As a direct and proximate result of the wrongful acts and omissions of Defendant, Plaintiff suffered severe injuries, emotional distress, and economic damages.

138. By reason of the foregoing, Plaintiff has sustained damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

139. WHEREFORE, Plaintiff demands judgment against Defendant for compensatory damages, for punitive damages, and for costs in excess of \$75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

DAMAGES

140. Plaintiff realleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

General and Special Damages

141. As a direct and proximate result of having the Advantage Fit pelvic mesh product implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury which includes or more likely than not may include, inter alia, any of the following: neuromuscular pain, obturator, ilioinguinal, and pudendal neuralgia, pelvic pain, groin pain, thigh pain, pelvic floor tension myalgia, Complex Regional Pain Syndrome (Type II), recurrent urinary tract infections, chronic dyspareunia, bowel and bladder dysfunction, and anorectal pain will likely undergo medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages. These injuries suffered by Plaintiff were caused by the wrongful acts and omissions of Defendant.

Punitive/Exemplary Damages

142. At all times relevant herein, Defendant:

- a. Knew that its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product, were dangerous, ineffective, and caused significant, life-altering complications and side-effects;

- b. Concealed the dangers and health risks from Plaintiff, physicians, hospitals, other medical providers, the FDA, its users and the public at large;
- c. Made misrepresentations to Plaintiff, physicians, hospitals, other medical providers, its users and the public at large as to the safety and efficacy of its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product; and
- d. With full knowledge of the health risks associated with its Pelvic Mesh Product, including the Advantage Fit pelvic mesh product, and without adequate warnings of the same, manufactured, designed, marketed, promoted, developed, sold and/or distributed its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product, for routine use.

143. Defendant, by and through its officers, directors, managing agents, authorized sales representatives, employees and/or other agents engaged in acts and/or omissions involving subjective awareness of an extreme degree of risk, indicating conscious indifference to the rights, safety, or welfare of others. As such, the conduct of Defendant warrants the imposition of punitive/exemplary damages pursuant to Ark. Code Ann. § 16-55-206 and under all applicable legal standards.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands trial by jury, and pray for judgment against Defendant as follows:

- 1. A judgment against Defendant holding it liable for compensatory damages in a reasonable amount determined to be fair and just by the jury in this cause sufficient to adequately compensate Plaintiff for her harms and losses, including but not limited to damages:

- a. For past and future general damages, the exact amount of which has yet to be ascertained, in an amount which will conform to proof at time of trial;
 - b. For past and future economic and special damages, according to proof at the time of trial;
 - c. For past and future medical and incidental expenses, according to proof at the time of trial;
 - d. For past and future loss of earnings and impaired earning capacity, according to proof at the time of trial;
 - e. For past and future physical impairment;
 - f. For past and future physical disfigurement; and
 - g. For past and future pain and suffering, as well as mental and emotional distress, according to proof at the time of trial.
2. For punitive and exemplary damages in a reasonable amount determined to be fair and just by the jury;
 3. For costs, attorneys' fees, interest, or any other relief, monetary or equitable, to which she is entitled; and
 4. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues in the above captioned matter.

DATE: December 21, 2021

Respectfully submitted,

/s/ Joseph N. Williams

Joseph N. Williams (#25874-49)
WILLIAMS & PIATT, LLC
301 Massachusetts Avenue, Suite 300
Indianapolis, IN 46204
(317) 633-5270
Fax: (317) 426-3348
joe@williamspiatt.com

BEN C. MARTIN
Texas Bar No. 13052400
(*pro hac vice* to be filed)
LAURA J. BAUGHMAN
(*pro hac vice* to be filed)
Texas Bar No. 00791846
RACHEL L. WRIGHT
(*pro hac vice* to be filed)
MARTIN BAUGHMAN, PLLC
3141 Hood Street, Level 6
Dallas, TX 75219
Office: 214.761.6614
Fax: 214.744.7590
bmartin@martinbaughman.com
lbaughman@martinbaughman.com
rwright@martinbaughman.com

ATTORNEYS FOR PLAINTIFF